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| **New product information**  |
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| ***Launched in the UK (or licence change for existing products)*** |
| Avapritinib (*Ayvakyt*) 100mg, 200mg and 300mg tablets | Monotherapy for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumours harbouring the platelet-derived growth factor receptor alpha D842V mutation |
| Baricitinib (*Olumiant*) 2mg and 4mg tablets | Treatment of active juvenile idiopathic arthritis in patients aged ≥2 years who have had an inadequate response or intolerance to one or more prior conventional synthetic or biologic disease-modifying antirheumatic drugs: polyarticular juvenile idiopathic arthritis (polyarticular rheumatoid factor positive or negative, extended oligoarticular), enthesitis related arthritis, and juvenile psoriatic arthritis (may be used as monotherapy or in combination with methotrexate) [new indication] |
| Baricitinib (*Olumiant*) 2mg and 4mg tablets | Treatment of moderate to severe atopic dermatitis in adult and paediatric patients aged ≥2 years who are candidates for systemic therapy [licence change from use only in adults] |
| Budesonide (*Kinpeygo*)4mg capsule | Treatment of primary immunoglobulin A nephropathy in adults at risk of rapid disease progression with a urine protein-to-creatinine ratio ≥1.5g/gram [new formulation] |
| Cladribine (*Mavenclad*)10mg tablet | Treatment of adults with relapsing forms of multiple sclerosis (MS) with active disease as defined by clinical or imaging features [licence change from use only in highly active relapsing MS] |
| COVID-19 vaccine (*Nuvaxovid XBB.1.5*) Multi-dose vial | Active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals aged ≥12 years |
| Dabigatran etexilate (*Pradaxa*) 20mg, 30mg, 40mg, 50mg, 110mg and 150mg granules in sachets | Treatment of venous thromboembolic events (VTE) and prevention of recurrent VTE in paediatric patients from the time the child is able to swallow soft food to <18 years of age [licence change from use from birth] |
| Dabrafenib (*Finlee*)10mg dispersible tablet | Use in combination with trametinib for the treatment of paediatric patients aged ≥1 year with low-grade glioma with a BRAF V600E mutation who require systemic therapy, and use in combination with trametinib for the treatment of paediatric patients aged ≥1 year with high-grade glioma with a BRAF V600E mutation who have received at least one prior radiation and/or chemotherapy treatment [new dispersible tablet formulation with a new indication] |
| Dupilumab (*Dupixent*) 300mg prefilled pen and prefilled syringe | Treatment of eosinophilic esophagitis in adults and adolescents aged ≥12 years, weighing ≥40kg, who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy [new indication] |
| Enalapril (*Aqumeldi*)0.25mg orodispersible tablet | Treatment of heart failure in children aged from birth to <18 years [new orodispersible tablet formulation] |
| Etrasimod (*Velsipity*)2mg tablet | Treatment of patients aged ≥16 years with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent |
| Hydroxycarbamide (*Xromi*) 100mg in 1mL oral solution | Prevention of vaso-occlusive complications of sickle cell disease in patients aged >9 months [licence change from use only in patients aged >2 years] |
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| **New product information**  |
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| ***Launched in the UK (or licence change for existing products)* (continued)** |
| Ivacaftor (*Kalydeco*)13.4mg granules in sachet | Use as monotherapy for the treatment of infants aged ≥1 month, toddlers and children weighing 3kg to <25kg with cystic fibrosis (CF) who have an R117H CFTR mutation or one of the following gating (class III) mutations in the CF transmembrane conductance regulator gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R, and use in a combination regimen with ivacaftor/tezacaftor/elexacaftor for the treatment of CF in paediatric patients aged 2 to <6 years who have at least one F508del mutation in the CFTR gene [new lower strength formulation] |
| Lanadelumab (*Takhzyro*) 300mg in 2mL prefilled syringe | Routine prevention of recurrent attacks of hereditary angioedema in patients aged ≥2 years [licence change from use only in patients aged ≥12 years] |
| Nonacog beta pegol (*Refixia*) 3,000unit vial | Treatment and prophylaxis of bleeding in patients of all ages with haemophilia B (congenital factor IX deficiency) [new 3,000unit strength formulation] |
| Povidone iodine 50mg in 1mL eye drops in 4mL bottle | For the pre-operative preparation of the surgical field (eyelids, lashes and cheeks) and irrigation of the ocular surface (cornea, conjunctiva and palpebral fornixes) [new formulation] |
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| **Regulatory changes in the UK or EU**  |
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| ***Approved in the UK*** |
| Baricitinib (*Olumiant*) 1mg tablet | Treatment of moderate to severe active rheumatoid arthritis in adults who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs) (may be used as monotherapy or in combination with methotrexate), treatment of moderate to severe atopic dermatitis in adult and paediatric patients aged ≥2 years who are candidates for systemic therapy, treatment of severe alopecia areata in adults, and treatment of active juvenile idiopathic arthritis in patients aged ≥2 years who have had an inadequate response or intolerance to one or more prior conventional synthetic or biologic DMARDs: polyarticular juvenile idiopathic arthritis (polyarticular rheumatoid factor positive or negative, extended oligoarticular), enthesitis-related arthritis, and juvenile psoriatic arthritis (may be used as monotherapy or in combination with methotrexate) [new lower strength tablet formulation] |
| Cefepime + enmetazobactam (*Exblifep*) 2g/0.5g vial | Treatment of the following infections in adults: Complicated urinary tract infections including pyelonephritis, hospital-acquired pneumonia including ventilator associated pneumonia, and treatment of patients with bacteraemia that occurs in association with, or is suspectedto be associated with, any of the infections listed above |
| Fosdenopterin (*Nulibry*) 9.5mg vial | Treatment of patients with molybdenum cofactor deficiency Type A |
| Ivermectin 3mg tablet | Treatment of gastrointestinal strongyloidiasis (anguillulosis), suspected or diagnosed microfilaraemia in patients with lymphatic filariasis due to Wuchereria bancrofti, and sarcoptic scabies, in adults and children weighing ≥15kg [Exeltis/Laboratorios Liconsa formulation] |
| Lanadelumab (*Takhzyro*) 150mg in 1mL prefilled syringe | Routine prevention of recurrent attacks of hereditary angioedema in patients aged ≥2 years [new lower dose formulation] |
| Latanoprost + timolol (*Vizilatan Duo*)50mg/5mg in 1mL eye drops | Use in adults (including the elderly) for the reduction of intraocular pressure in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues |
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| **Regulatory changes in the UK or EU**  |
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| ***Approved in the UK* (continued)** |
| Liraglutide biosimilar (*Nevolat*)18mg in 3mL prefilled pen | Use as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adults with an initial Body Mass Index (BMI) of ≥30kg/m² (obesity), or ≥27kg/m² to <30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. Also use as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescents aged ≥12 years with obesity (BMI corresponding to ≥30kg/m2 for adults by international cut-off points) and body weight >60kg. |
| Liraglutide biosimilar (*Zegluxen*)18mg in 3mL prefilled pen | Use for the treatment of adults, adolescents and children aged ≥10 years with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or contraindications and in addition to other medicinal products for the treatment of diabetes |
| Talazoparib (*Talzenna*) 100microgram capsule | For use as monotherapy for the treatment of adults with germline BRCA1/2-mutations, who have HER2-negative locally advanced or metastatic breast cancer. Patients should have been previously treated with an anthracycline and/or a taxane in the (neo)adjuvant, locally advanced or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine-based therapy, or be considered unsuitable for endocrine-based therapy. Also for use in combination with enzalutamide for the treatment of adults with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated. [new lower strength formulation] |
| Ustekinumab biosimilar (*Uzpruvo*)45mg in 0.5mL and 90mg in 1mL prefilled syringes | Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A); treatment of moderate to severe plaque psoriasis in children and adolescent patients aged ≥6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies; use alone or in combination with MTX for treatment of active psoriatic arthritis in adults when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate; and treatment of adults with moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies |
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| ***Recommended for approval in the UK or EU*** |
| Alectinib (*Alecensa*) | Use as monotherapy for adjuvant treatment following complete tumour resection for adults with ALK‑positive non-small cell lung cancer at high risk of recurrence [EU] [new indication] |
| Amivantamab (*Rybrevant*) | Use in combination with carboplatin and pemetrexed for the first‑line treatment of adults with advanced non-small cell lung cancer with activating EGFR Exon 20 insertion mutations [EU] [new indication] |
| Aprocitentan (*Jeraygo*) | Treatment of resistant hypertension in adults in combination with at least three antihypertensive medicinal products [EU] |
| Bedaquiline (*Sirturo*) | Use as part of an appropriate combination regimen in adults and paediatric patients (aged 5 years to <18 years and weighing ≥15kg) with pulmonary tuberculosis (TB) due to *Mycobacterium tuberculosis* resistant to at least rifampicin and isoniazid [EU] [licence change from use only in multi-drug resistant TB when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability] |
| Capivasertib (*Truqap*) | Use in combination with fulvestrant for the treatment of adults with oestrogen receptor-positive, HER2‑negative locally advanced or metastatic breast cancer with one or more PIK3CA/AKT1/PTEN-alterations following recurrence or progression on or after an endocrine-based regimen [EU] |
| Dolutegravir + abacavir + lamivudine (*Triumeq*) | Treatment of Human Immunodeficiency Virus type 1 infected children aged ≥3 months weighing ≥6kg to <25kg [EU] [licence change for dispersible tablets from use only in children weighing ≥14kg to <25kg] |
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| **Regulatory changes in the UK or EU**  |
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| ***Recommended for approval in the UK or EU* (continued)** |
| Efanesoctocog alfa (*Altuvoct*) | Treatment and prophylaxis of bleeding in patients of all ages with haemophilia A (congenital factor VIII deficiency) [EU] |
| Entrectinib (*Rozlytrek*) | Use as monotherapy for the treatment of adult and paediatric patients aged >1 month with solid tumours that have a NTRK gene fusion, who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and who have not received a prior NTRK inhibitor who have no satisfactory treatment options [EU] [licence change from use only in patients aged ≥12 years] |
| Entrectinib (*Rozlytrek*) | Use as monotherapy for the treatment of adult and paediatric patients aged >1 month with solid tumours that have a NTRK gene fusion, who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and who have not received a prior NTRK inhibitor who have no satisfactory treatment options. Also use as monotherapy for the treatment of adult patients with ROS1‑positive, advanced non-small cell lung cancer not previously treated with ROS1 inhibitors. [EU] [new gastroenteral route of administration for the 100 and 200 mg hard capsules] |
| Entrectinib (*Rozlytrek*) | Use as monotherapy for the treatment of adult and paediatric patients aged >1 month with solid tumours that have a NTRK gene fusion, who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and who have not received a prior NTRK inhibitor who have no satisfactory treatment options. Also use as monotherapy for the treatment of adult patients with ROS1‑positive, advanced non-small cell lung cancer not previously treated with ROS1 inhibitors. [EU] [new granules in capsule formulation] |
| Fruquintinib (*Fruzaqla*) | Monotherapy for the treatment of adults with metastatic colorectal cancer who have been previously treated with available standard therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan‑based chemotherapies, anti‑VEGF agents, and anti‑EGFR agents, and who have progressed on or are intolerant to treatment with either trifluridine‑tipiracil or regorafenib [EU] |
| Nivolumab (*Opdivo*) | Use in combination with cisplatin and gemcitabine for the first-line treatment of adults with unresectable or metastatic urothelial carcinoma [EU] [new indication] |
| Tocilizumab biosimilar (*Tofidence*) | Use in combination with methotrexate (MTX) for the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX and the treatment of moderate to severe active RA in adults who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease- modifying anti-rheumatic drugs or tumour necrosis factor antagonists [EU] [IV formulation] |
| Ustekinumab biosimilar (*Wezenla*) | Treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or PUVA (psoralen and ultraviolet A); treatment of moderate to severe plaque psoriasis in children and adolescent patients aged ≥6 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies; use alone or in combination with MTX for the treatment of active psoriatic arthritis in adults when the response to previous non-biological disease-modifying anti-rheumatic drug therapy has been inadequate; treatment of adults with moderately to severely active Crohn’s disease who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies [EU] [SC and IV formulations] |
| Vibegron (*Obgemsa*) | Symptomatic treatment of adults with overactive bladder syndrome [EU] |
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| **Regulatory changes in the UK or EU**  |
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| ***Filed for approval in the UK or EU*** |
| Aflibercept biosimilar – SCD411 | Wet age-related macular degeneration in adults, and other *Eylea* indications (to be confirmed) [EU] |
| Alectinib (*Alecensa*) | Use as monotherapy for adjuvant treatment following complete tumour resection for adults with ALK‑positive non-small cell lung cancer at high risk of recurrence [UK] [new indication] |
| Bosutinib (*Bosulif*) | Treatment of paediatric patients aged ≥1 year with newly-diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukaemia [EU] [licence change from use only in adults and new 50mg and 100mg capsule formulations] |
| Ferric citrate coordination complex (*Fexeric*) | Control of hyperphosphataemia in adults with chronic kidney disease [EU] |
| Letermovir (*Prevymis*) | Prophylaxis of cytomegalovirus (CMV) reactivation and disease in adult and paediatric (from birth up to 18 years old) CMV-seropositive recipients [R+] of an allogeneic haematopoietic stem cell transplant [EU] [licence change from use only in adults and new 20mg and 120mg granules in sachet formulations] |
| Liraglutide biosimilar (*Nevolat*) | Use as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adults with an initial Body Mass Index (BMI) of ≥30kg/m² (obesity), or ≥27kg/m² to <30kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (pre-diabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. Also use as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescents aged ≥12 years with obesity (BMI corresponding to ≥30kg/m2 for adults by international cut-off points) and body weight >60kg. [EU] *Note: Already approved in UK* |
| Liraglutide biosimilar (*Zegluxen*) | Use for the treatment of adults, adolescents and children aged ≥10 years with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or contraindications and in addition to other medicinal products for the treatment of diabetes [EU] *Note: Already approved in UK* |
| Mozafancogene autotemcel | Type A Fanconi anaemia in adolescents and children aged ≥1 year with no HLA-identical sibling donor [EU] |
| Obecabtagene autoleucel  | Treatment of adults with relapsed or refractory B cell precursor acute lymphoblastic leukaemia [EU] |
| Pegcetacoplan (*Syfovre*) | Treatment of geographic atrophy secondary to age-related macular degeneration in adults [EU] [EMA CHMP to restart its evaluation following a legal judgement] |
| Pembrolizumab (*Keytruda*) | Use in combination with carboplatin and paclitaxel for the first-line treatment of primary advanced or recurrent endometrial carcinoma in adults [EU] [new indication] |
| Pirtobrutinib (*Jaypirca*) | Treatment of adults with chronic lymphocytic leukemia who have been previously treated with a Bruton’s tyrosine kinase inhibitor [EU] [new indication] |
| Pneumococcal conjugate vaccine  | Active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* [EU] [new 21-valent formulation] |
| Turoctocog alfa pegol (*Esperoct*) | Treatment and prophylaxis of bleeding in patients of all ages with haemophilia A (congenital factor VIII deficiency) [EU] [licence change from use only in patients aged ≥12 years] |
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| ***Other UK/EU developments*** |
| Edaravone  | Early-stage amyotrophic lateral sclerosis in adults – development discontinued (lack of efficacy) |
| Sodium phenylbutyrate + ursodoxicoltaurine (*Albrioza*) | Early-stage amyotrophic lateral sclerosis in adults – development discontinued (lack of efficacy) |
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